K030395

Section E

APR 0 8 2003

510(k) Summary

A. General Provisions

Submitter's Name: Empi Corp.
Submitter's Address: 599 Cardigan Road
St. Paul, Minnesota 55126-3965
Contact Person: Suzan Onel and Donald R. Stone
(202) 778-9000 (ph); (202) 778-9100 (fax)

Classification Name: Iontophoresis Device
21 CFR 890.5525
Proprietary Name: Empi Act*ion* Patch Iontophoresis System (also known as the "Act*ion* Patch")
Common Name: Iontophoresis Device

B. Date of preparation of this Summary: January 31, 2003

C. Name of Predicate Devices to which equivalence is claimed:

- Birch Point IontoPatch K992708
- Empi Dupel B.L.U.E. Iontophoresis Electrode K983484
- Empi Dupel Dual-Chamber Iontophoresis System K915444
- Empi Buffered Iontophoresis Electrodes K912015

The Empi Act*ion* Patch is substantially equivalent to the identified Empi Dupel iontophoresis devices in intended use, materials of construction, and mode of operation. The Empi Act*ion* Patch is substantially equivalent to the Birch Point IontoPatch in terms of intended use and self contained design. The Act*ion* Patch uses the identical adhesive foam backing as that used in the Empi Buffered Iontophoresis Electrodes.

D. Device Description

The Empi Act*ion* Patch Iontophoresis System is a disposable single-use iontophoresis device with a self-contained battery and electrical circuitry. A single adhesive patch unifies both the battery-powered iontophoresis device and the active and return electrodes. The Empi Act*ion* Patch is designed to deliver a calibrated and fixed dose of ionic solution (between 1 and 160 mAmp * min.) over a specified time. After delivery of the specified dose, an LED indicator light extinguishes indicating that that the Patch can be removed.

E. Statement of Intended Use Compared to Predicate Device(s)

The Empi Act*ion* Patch has the same intended use as the above identified predicate devices and other iontophoresis devices, i.e., it is intended to be used for the local administration of ionic solutions into the body for medical purposes and as an alternative to injections.

F. Discussion of Technological Characteristics:

Like the Birch Point IontoPatch, the Empi Act*ion* Patch is a disposable, self-contained, single use iontophoresis device in a unified patch form. In terms of outward appearance and intended use, it is substantially equivalent to the IontoPatch. In terms of design, both incorporate a battery to supply current to the electrodes and a means of electronically controlling a fixed dose (current * time). Both devices extend the duration of an iontophoresis session beyond that typical for multiple component systems, such as the Empi Dupel iontophoresis system designed to be used during a clinic visit. Since the duration is longer, both unified patch devices require a maximal output voltage that is less than predicate multicomponent systems such as the Dupel. The IontoPatch outputs 1 volt, and the Act*ion* Patch produces 10.5 volts: both significantly less than the maximal voltage of the Dupel system of 60 volts. This adds an intrinsic safety factor to both unified patch devices in that the maximal current density is also less than that of the predicate multicomponent devices designed for shorter iontophoresis sessions.

The Empi Act*ion* Patch uses an immobilized buffer system to control pH, a major determinant of chemical safety during iontophoresis. This buffering system is identical to the Dupel B.L.U.E. iontophoresis electrode in terms of mechanism of action, materials, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Empi Corporation
c/o Ms. Suzan Onel
Kirkpatrick & Lockhart LLP
1800 Massachusetts Avenue, NW
Suite 200
Washington, DC 20036-1221

APR 0 8 2003

Re: K030395
Trade/Device Name: EMPI Action Patch Iontophoresis System
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: February 5, 2003
Received: February 5, 2003

Dear Ms. Onel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to drugs for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594- 4659. Also, please note the regulation entitled, "Misbranding by

reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Appendix A1

510(k) Number (if known):

Device Name: Empi Act*ion* Patch Iontophoresis System

Indications for Use:

The Empi Act*ion* Patch Iontophoresis System is indicated for the local administration of ionic solutions into the body for medical purposes and can be used as an alternative to injections.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030395 mnm
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Prescription Use _____ OR Over-The Counter Use _____

(Per 21 CFR 801.109)